maine standards COMPANY

JUN 1 4 2013

510(k) SUMMARY

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92."

"The assigned 510(k) number is: K123127."

Submitter: Maine Standards Company
Address: 765 Roosevelt Trail
Windham, ME 04062

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Contact: James Champlin

Summary prepared on: June 14, 2013

Device classification name: Multi-Analyte Controls, All Kinds (Assayed and Unassayed)
Device description: Quality control material (assayed and un-assayed)*

Proprietary Name: VALIDATE® PSA Calibration Verification / Linearity Test Kit

Regulation Number: 21 CFR 862.1660

Product Code: JJX*
***Note**: There is no FDA product code for calibration verification / linearity materials. Therefore, as with previous submissions by Maine Standards Company and other calibration verification / linearity manufacturers, JJX was selected as the "best fit" FDA code for this product.*

Regulatory Class: Class I

Predicate Device:
VALIDATE® Chem 6 Calibration Verification / Linearity Test Kit, Maine Standards Company, Windham, ME.

Device description: Each VALIDATE® PSA Calibration Verification / Linearity Test Kit contains purified chemicals in a human serum base. Multiple levels are provided to establish the relationship between theoretical and actual performance of each of the included analytes.

Intended use:
VALIDATE PSA Calibration Verification / Linearity Test Kit solutions are intended for *in vitro* diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range for the following analytes: Total prostate-specific antigen (PSA) and free prostate-specific antigen (fPSA) on automated systems.

Summary:
The VALIDATE® PSA Calibration Verification / Linearity Test Kit behave in a manner suitable for the evaluation of calibration verification, verification of reportable range, and the linear response of the listed analytes over the ranges tested when compared to the predicate device. VALIDATE® PSA Calibration Verification / Linearity Test Kit is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 14, 2013

MAINE STANDARDS COMPANY, LLC
C/O MR. JAMES W. CHAMPLIN
MANAGER, QA & RA
765 ROOSEVELT TRAIL
WINDHAM ME 04062

Re: K123127
Trade/Device Name: VALIDATE PSA Calibration Verification/ Linearity Test Kit
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: II
Product Code: JJX
Dated: May 24, 2013
Received: May 24, 2013

Dear Mr. Champlin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Maria M. Chan -S

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123127

Device Name: VALIDATE® PSA Calibration Verification / Linearity Test Kit

Indications For Use:

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Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Maria M. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

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